

**REMARKS****STATUS OF THE CLAIMS**

With this amendment, claims 1 and 2 are pending in the present application and under examination. Claims 22 and 23 are canceled. Claims 3-21 and 24-82 are withdrawn as being drawn to non-elected inventions.

Claim 1 has been amended to recite "a computer database containing SEQ ID NO: 1" and to recite an additional step of "outputting the identified amino acid sequence." Support for these amendments can be found throughout the specification, *e.g.*, at page 7, seventh paragraph, and page 8, first three paragraphs. By way of example, page 8, third paragraph, cites various common algorithms or programs for ORF identification. These identify ORFs by first scanning the entire sequence for initiation codons and then scanning sequences downstream of the initiation codon for in-frame termination codons. Once the ORFs have been identified, these programs have as an inherent step of outputting the identified amino acid sequence that one of skill in the art would recognize is the final step of these programs. For the Examiner's convenience, Salzberg *et al.* (1998) *Nucl Acids Res* 26:544-548 has been included herewith in a supplemental information disclosure statement. Salzberg *et al.* discuss the program system GLIMMER disclosed on page 8, paragraph 3 of the specification. Salzberg *et al.* on page 547, col. 1, paragraph 2 indicate that, "[t]he final output of the program is a list of putative gene coordinates in the genome, together with notations for each one that may have has a suspicious overlap with another gene candidate." One of skill in the art would also recognize that the form of output varies from program to program. For example, some programs output the results by displaying on a screen, and other programs output by saving to computer readable media. Thus, Applicants assert that there is adequate support in the specification for these amendments and that no new matter has been added.

Applicant respectfully request that the Examiner enter the proposed amendment as it puts the claims in condition for allowance and in better position for appeal. In addition, the Applicants note that they could not have made the amendment previously as the Examiner only

provided the specificity for the Section 101 rejection in the final Office Action issued March 10, 2006 indicating that the lack of outputting the final answer was considered relevant to the rejection.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

### **REJECTION OF CLAIMS UNDER 35 U.S.C § 101**

Claims 1 and 2 have been rejected under 35 U.S.C. § 101 as allegedly being directed to nonpatentable subject matter. Specifically, the Examiner asserts that the method claimed is merely a mathematical algorithm without concrete or tangible steps (*i.e.*, no physical steps).

This rejection is respectfully traversed. First, the Examiner has asserted that “(a) Searching for putative open reading frames within SEQ.ID.NO:1 and identifying a sequence which corresponds to ORF does generate a final result where one who practices the method would obtain a final answer.” The claims as amended provide that a final answer, *i.e.*, the identified amino acid sequence, is output. Thus, one of skill in the art will receive a final answer, which is clear useful.

Second, the Examiner has asserted that “(b) The method claims merely retrieve previously known ORF sequences from databases.” This assertion is not correct. SEQ ID NO:1 is a novel sequence, therefore it has ORFs that have never been identified. Thus, the claimed method will produce ORFs that were previously unknown. Further, the method is not directed to retrieving an ORF from a database containing known ORFs, the method is directed to searching for ORFs in a nucleic acid sequence (SEQ ID NO:1) which is in a database.

Third, the Examiner has asserted in support of the assertion that the method does not provide a concrete, tangible and useful result that “(c) There is no transformation of data, or generation of a concrete, tangible and useful result.” This is merely a restatement of the test, rather

than a citation or specific reasons why the claimed method does not provide a concrete, tangible and useful result.

Furthermore, the claimed method leads to a “useful, tangible, and concrete” result, which is sufficient to demonstrate that it is patentable subject matter. As noted in the recently issued Guidelines, the mere fact that a claim includes a § 101 judicial exception (such as an abstract idea or mathematical algorithm) does not mean that the claimed invention itself is nonpatentable subject matter. *See* Guidelines at 18. In particular, the Guidelines emphasize that a claimed invention that employs a mathematical algorithm to create a “useful, tangible, and concrete” result is patentable regardless of the fact that the invention includes nonstatutory subject matter. *See* Guidelines at 20. The focus is not on whether the *steps* taken to achieve a particular result are useful, tangible, and concrete, but rather on whether the *result* itself is “useful, tangible, and concrete.” *See* Guidelines at 20.

The claimed invention is a method of identifying an amino acid comprising searching for putative ORFs within SEQ ID NO:1, identifying the amino acid sequence corresponding to the putative ORFs and outputting the identified amino acid sequence. The result of this claimed method is therefore amino acid sequences which can serve as antigens for a meningitis vaccine, a result that is both “tangible” and “useful”. In addition, this result is “concrete.” A “concrete” result is one that is substantially repeatable. *See* Guidelines at 22. As taught in the specification, ORFs or protein-coding sequences can be identified via various algorithms. Each algorithm takes into account various characteristics of the nucleotide sequence in order to identify likely protein-coding sequences. However, all of these algorithms take into account the presence of start and stop codons, which are one of the major determinants for locating protein-coding regions. Thus, even though each algorithm factors in different characteristics and therefore will not identify exactly the same ORFs as another algorithm, it will nevertheless identify substantially the same ORFs as other algorithms. Furthermore, each individual algorithm will reproducibly identify the same ORFs as long as the same input parameters are used. Therefore, the result of the claimed method is substantially repeatable, regardless of the particular algorithm used to carry out the searching process. Accordingly, Applicants respectfully submit that the claimed invention employs a

mathematical algorithm to produce a “useful, tangible, and concrete” result and is therefore patentable subject matter.

In view of the above remarks, Applicants respectfully request that this rejection be withdrawn. If the Examiner maintains the rejection, Applicants respectfully request that the Examiner provide specificity as to which of the three elements of the test set forth in the Guidelines the Examiner feels that the claimed invention is not meeting, i.e., why the Examiner feels that the claimed invention does not produce a “useful” result, etc.

## **REJECTION OF CLAIMS UNDER 35 U.S.C. § 102**

### **Rejection under 35 U.S.C. § 102(b) by Ribot (WO 98/17805)**

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ribot (WO 98/17805). This rejection and its supporting remarks are respectfully traversed.

Applicants respectfully disagree with the Examiner’s rejection and its supporting remarks. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to recite a computer database containing SEQ ID NO:1. With the amendment, the claims require searching a computer database containing SEQ ID NO:1 which is essentially the *Neisseria meningitidis* genome as the applicants have been arguing. Applicants recognize that “the entire *Neisseria meningitidis* genome” is not an element of the claims; however, SEQ ID NO:1 is a 2,242,716 base sequence that was generated by sequencing the full genome of *Neisseria meningitidis*. Ribot does not teach a computer database containing SEQ ID NO:1 and therefore lack an element of the present claims. The sequence listing of Ribot contains fifteen sequences with the longest nucleic acid sequence being a mere 5,416 base pairs. Thus, Ribot does not disclose any nucleic acid sequence of 2,242,716, much less SEQ ID NO:1 as is presently claimed, therefore Ribot cannot anticipate the present claims. It is well accepted that “a claim is anticipated only if each and every element is set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of*

*California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants therefore respectfully request that the Examiner withdraw this rejection.

**Rejection under 35 U.S.C. § 102(b) by Brodeur (WO 96/29412)**

Claims 1 and 2 were also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brodeur (WO 96/29412). This rejection and its supporting remarks are respectfully traversed.

Applicants respectfully disagree with the Examiner's rejection and its supporting remarks. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to recite a computer database containing SEQ ID NO:1. With the amendment, the claims require searching the entire what is essentially the *Neisseria meningitidis* genome as the applicants have been arguing. Applicants recognize that "the entire *Neisseria meningitidis* genome" is not an element of the claims; however, SEQ ID NO:1 is a 2,242,716 base sequence that was generated by sequencing the full genome of *Neisseria meningitidis*. Brodeur does not teach a computer database containing SEQ ID NO:1 and therefore lack an element of the present claims. The sequence listing of Brodeur contains twenty-six sequences with the longest nucleic acid sequence being a mere 850 base pairs. Thus, Brodeur does not disclose any nucleic acid sequence of 2,242,716, much less SEQ ID NO:1 as is presently claimed, therefore Brodeur cannot anticipate the present claims. It is well accepted that "a claim is anticipated only if each and every element is set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants therefore respectfully request that the Examiner withdraw this rejection.

**Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1 and 2 were also rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. This rejection and its supporting remarks are respectfully traversed.

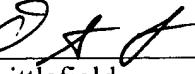
The Examiner has asserted that the step of “identifying an amino acid sequence corresponding to the searched putative open reading frames or protein-coding sequences” is indefinite because the claim does not specify the method whereby the amino acid sequence is identified. However, once an open reading frame or protein coding sequence has been found by searching a nucleic acid sequence, it is a trivial matter for one of skill in the art to identify the corresponding amino acid sequence. At the simplest level, all that is required is rote application of the genetic code for the organism, in this case *Neisseria meningitidis* to identify the corresponding amino acid sequence. If one of skill in the art wishes to use some more elaborate method that will identify the corresponding amino acid sequence such by sequence alignment as suggested by the Examiner, then one of skill in the art may also use such method or any other method available to one of skill in the art. Thus, applicants respectfully assert that the step is definite and request that the Examiner withdraw the pending rejection of claims 1 and 2 under 35 U.S.C. § 112, second paragraph.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **223002100400**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 20, 2006

Respectfully submitted,

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